



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Wright Medical Technology, Inc.
Mr. Val Myles
Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

November 20, 2014

Re: K142585

Trade/Device Name: PhaLinx Hammertoe System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener.
Regulatory Class: Class II
Product Code: HWC
Dated: September 12, 2014
Received: September 15, 2014

Dear Mr. Val Myles:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142585

Device Name

PhaLinx® Hammertoe System

Indications for Use (Describe)

The PhaLinx® Hammertoe System is designed for small bone fusion and fractures. It is indicated for fractures, and inter-digital fusion of the fingers, toes and small bones.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the WMT PhaLinx® Hammertoe System.

- (a)(1). Submitted By:** Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117
- Date:** November 10, 2014
- Contact Person:** Val Myles
Regulatory Affairs Specialist
Office - (901) 290-5162
Fax – (901) 867-4190
- (a)(2). Proprietary Name:** PhaLinx® Hammertoe System
- Common Name:** Smooth or threaded metallic bone fixation fastener
- Classification Name and Reference:** 21 CFR 888.3040 – Class II
- Device Product Code, Device Panel:** HWC – Orthopedic
- (a)(3). Predicate Device:** K113006: I-Fuse Hammer Toe Systems
K022599: NEWDEAL® K WIRE
K132895 & K140148: WMT Implantable K-Wires
- (a)(4). Device Description**
The PhaLinx® Hammertoe System implants are a single piece titanium device offered in straight cannulated and 10° solid options. The implants have proximal and distal fixation features and are offered in multiple sizes.
- (a)(5). INTENDED USE**
The PhaLinx® Hammertoe System is designed for small bone fusion and fractures. It is indicated for fractures, and inter-digital fusion of the fingers, toes and small bones.
- (a)(6). Technological Characteristics Comparison**

The PhaLinx® Hammertoe System and the legally marketed predicate devices have similar indications, dimensions and geometry, and materials. The PhaLinx® Hammertoe System is technologically substantially equivalent to the predicate devices.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Testing related to bending and pull-out strength were provided to support the substantial equivalence of the subject device and show that no new worst-case devices are introduced in this system.

The safety and effectiveness of the PhaLinx® Hammertoe System is adequately supported by the mechanical testing, substantial equivalence information, materials information and comparison of design characteristics provided within this premarket notification. Through the analysis of technical characteristics the new devices are substantially equivalent to the predicate devices.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate device.